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| APPLICATION NO.         | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|----------------|----------------------|---------------------|------------------|
| 09/453,109              | 12/02/1999     | MARK R. PRAUSNITZ    | BVTP-P01-539 2183   |                  |
| 28120                   | 7590 04/25/200 | 7                    |                     |                  |
| FISH & NEAV             |                | EXAMINER             |                     |                  |
| ROPES & GRA             | AY LLP         | WINAKUR, ERIC FRANK  |                     |                  |
| ONE INTERNATIONAL PLACE |                |                      | ART UNIT            | PAPER NUMBER     |
| BOSTON, MA              | X 02110-2624   |                      | 3768                |                  |
| • •                     |                |                      | 3706                |                  |
|                         |                |                      |                     |                  |
|                         |                |                      | MAIL DATE           | DELIVERY MODE    |
|                         |                |                      | 04/25/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s)     |                  |  |  |
|-----------------|------------------|------------------|--|--|
| 09/453,109      | PRAUSNITZ ET AL. | PRAUSNITZ ET AL. |  |  |
| Examiner        | Art Unit         |                  |  |  |
| Eric F. Winakur | 3768             |                  |  |  |

| Bereie the rining of an Appeal Brief   | Examiner  | Art Unit   |                |  |  |  |  |
|--|---|--|----------------|--|--|--|--|
|  | Eric F. Winakur   | 3768   |                |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |   |  |                |  |  |  |  |
| THE REPLY FILED 4/12/07 FAILS TO PLACE THIS APPLICA  | TION IN CONDITION FOR ALLOW   | ANCE.  |                |  |  |  |  |
| 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:  |   |  |                |  |  |  |  |
| b) The period for reply expires on: (1) the mailing date of this A   | <ul> <li>a) The period for reply expiresmonths from the mailing date of the final rejection.</li> <li>b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.</li> </ul> |  |                |  |  |  |  |
| Examiner Note: If box 1 is checked, check either box (a) or TWO MONTHS OF THE FINAL REJECTION. See MPEP 7  | 06.07(f).   |  |                |  |  |  |  |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  NOTICE OF APPEAL |   |  |                |  |  |  |  |
| 2. The Notice of Appeal was filed on <u>09 February 2007</u> . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).   |   |  |                |  |  |  |  |
| AMENDMENTS 3. ☑ The proposed amendment(s) filed after a final rejection,   | but prior to the date of filing a brief   | will not be entered b                                | ecause         |  |  |  |  |
| (a) $oxed{\boxtimes}$ They raise new issues that would require further co  | nsideration and/or search (see NO   |  | coausc         |  |  |  |  |
| <ul> <li>(b) ☐ They raise the issue of new matter (see NOTE below</li> <li>(c) ☐ They are not deemed to place the application in be appeal; and/or</li> </ul>  | • •   | ducing or simplifying                                | the issues for |  |  |  |  |
| (d) They present additional claims without canceling a   |   | ected claims.  |                |  |  |  |  |
| NOTE: <u>See Continuation Sheet</u> . (See 37 CFR 1.1  | * **  |  | (570)          |  |  |  |  |
| <ul> <li>4.  The amendments are not in compliance with 37 CFR 1.1</li> <li>5.  Applicant's reply has overcome the following rejection(s)</li> </ul>  |   | empliant Amendment                                   | (PTOL-324).    |  |  |  |  |
| Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).   |   |  |                |  |  |  |  |
| 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  The status of the claim(s) is (or will be) as follows:  Claim(s) allowed: 47-55.   |   |  |                |  |  |  |  |
| Claim(s) objected to: <u>5,8,9,13,26,38,39,42 and 43</u> . Claim(s) rejected: <u>1-4,6,7,10-12,14-18,20-22,24,25,27-37</u> Claim(s) withdrawn from consideration:  | 7,40,41 and 44-46.  |  |                |  |  |  |  |
| AFFIDAVIT OR OTHER EVIDENCE  | Abore a la com a  |  |                |  |  |  |  |
| <ol> <li>The affidavit or other evidence filed after a final action, be<br/>because applicant failed to provide a showing of good an<br/>was not earlier presented. See 37 CFR 1.116(e).</li> </ol>  |   |  |                |  |  |  |  |
| 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).   |   |  |                |  |  |  |  |
| 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.  REQUEST FOR RECONSIDERATION/OTHER  |   |  |                |  |  |  |  |
| 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:   |   |  |                |  |  |  |  |
| 12. Note the attached Information Disclosure Statement(s).   | (PTO/SB/08) Paper No(s)   |  |                |  |  |  |  |
| 13.  Other:  |   | 53   |                |  |  |  |  |
|  |   | FrieFM   |                |  |  |  |  |
| ·  |   | Eric F Winakur<br>Primary Examiner<br>Art Unit: 3768 |                |  |  |  |  |

Continuation of 3. NOTE: As Applicant notes in the remarks, three new independent claims were included with the proposed amendment which recite features allegedly not found in the cited art (in particular, a porous microneedle, a microneedle comprising a polymer, and a substrate and/or microneedle made from a flexible material are found in the three newly added claims, respectively). These newly added features constitute new issues that would require further search and consideration. In addition, Applicant has updated the dependencies of certain dependent claims, which at least requires consideration of adequacy of disclosure under 112, first paragraph of any previously unclaimed combinations of features.